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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,741	11/27/2001	Brigitte C. Phan	111465.129	3682

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EXAMINER
LU, FRANK WEI MIN

ART UNIT 1634	PAPER NUMBER
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DATE MAILED: 08/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/997,741

Applicant(s)

PHAN ET AL.

Examiner

Frank W Lu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) 5,6,8,12 and 29-60 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4,7,9,13,14,22 and 26-28 is/are rejected.
- 7) ☒ Claim(s) 10,11,15-21 and 23-25 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 4/9/2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group I, claims 1-28, and species 1 (claim 4), species 4 (claim 7), and species 6 (claims 10 and 11) filed on August 2, 2004 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, claims 1-4, 7, 9-11, and 13-28 will be examined.

Specification

2. The abstract of the disclosure is objected to because it exceeds 150 words in length. Correction is required. See MPEP § 608.01(b).

Claim Objections

3. Claim 24 is objected to because of the following informality: "the first and second groups being different" should be "the first group of capture beads and the second group of capture beads being different".

4. Claim 25 is objected to because of the following informality: "the first and second groups being different" should be "the first group of reporter beads and the second group of reporter beads being different".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
6. Claims 2-4, 7, 9, 13, 14, 22, and 26-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
7. Claim 2 is rejected as vague and indefinite in view of the phrase “the isolating includes subjecting the mixture to a magnetic field” since this phrase is incomplete. The examiner suggests to change “the isolating includes subjecting the mixture to a magnetic field” to “the isolating the dual bead complex includes subjecting the mixture to a magnetic field”. Please clarify.
8. Claims 3 and 4 are rejected as vague and indefinite. Since exposing step (on a disc) in claim 1 is after isolating step of claim 1, in view of claim 2, the magnetic field must be applied before the capture beads and reporter beads are on the disc. Therefore, the phrase “the magnetic field is applied while the capture beads and reporter beads are on the disc” recited in claim 3 and the phrase “the capture beads and reporter beads are mixed off the disc and the magnetic field is applied to the mixture of the sample and the beads off the disc” recited in claim 4 do not make sense. Please clarify.
9. Claim 7 is rejected as vague and indefinite in view of the phrase “the detecting includes directing light to the capture field and detecting light reflected from the capture field” since this phrase is incomplete. The examiner suggests to change “the detecting includes directing light to the capture field and detecting light reflected from the capture field” to “the detecting the

presence of the dual bead complex includes directing light to the capture field and detecting light reflected from the capture field”. Please clarify.

10. Claim 9 is rejected as vague and indefinite in view of the phrase “the reporter beads are fluorescent, the detecting including directing light at a wavelength at which the reporter beads fluoresce, and detecting light at a wavelength emitted by the reporter beads” since this phrase is unclear. The examiner suggests to change “the reporter beads are fluorescent, the detecting including directing light at a wavelength at which the reporter beads fluoresce, and detecting light at a wavelength emitted by the reporter beads” to “the reporter beads have fluorescent labels, the detecting including directing light at a wavelength at which the fluorescent label is excited, and detecting light at a wavelength at which the fluorescent label is emitted”. Please clarify.

11. Claim 13 is rejected as vague and indefinite because it is unclear that the biological sample in claim 1 includes all samples in claim 13 or a biological sample in claim 1 is selected from one of the samples in claim 13. Please clarify.

12. Claim 14 is rejected as vague and indefinite because it is unclear what it intended. The examiner suggests to change “the reporter bead includes latex, gold, plastic, steel, or titanium” to “the reporter bead is made by latex, gold, plastic, steel, or titanium”. Please clarify.

13. Claim 22 is rejected as vague and indefinite because it is unclear that the target agent in claim 1 includes all nucleic acids in claim 22 or the target agent in claim 1 is selected from one of nucleic acids in claim 22. Please clarify.

14. Claim 26 is rejected as vague and indefinite because it is unclear what means “a

second capture field fluidly coupled to the first capture field". What kind of coupling can be called as "fluidly" coupling? Please clarify.

15. Claim 26 is rejected as vague and indefinite. Since claim 1 only requires one capture field while claim 26 has two capture fields, claims 1 and 26 do not correspond each other. Please clarify.

16. Claims 27 and 28 are rejected as vague and indefinite. Since claim 1 only requires one capture field and one capture agent while claims 27 and 28 has two capture fields and two capture agents, claim 1 and claims 27 and 28 do not correspond each other. Please clarify.

Double Patenting

17. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claim 1 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No.10/087,549. Although the conflicting claims are not identical, they are not patentably distinct from each other because the examined claims in this instant application is either anticipated by, or would have been obvious over, the reference claims. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969). Although claim 1 in this instant application are not identical to claim 1 of copending Application No.10/087,549, claim 1 in copending Application No.10/087,549 are directed to the same subject matter and fall entirely within the scope of claim 1 in this instant application. In other words, claim 1 in this instant application is anticipated by claim 1 of copending Application No.10/087,549.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

19. No claim is allowed.
20. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30

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(November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is either (703) 872-9306.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746.

The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (571)272-0782.

Any inquiry of a general nature or relating to the status of this application should be directed to the Chemical Matrix receptionist whose telephone number is (703) 308-0196.

Frank Lu
PSA
August 23, 2004


FRANK LU
PATENT EXAMINER